LIFE, LIBERTY & THE PURSUIT OF PUBLIC HEALTH

Reflections on Immunization Requirements

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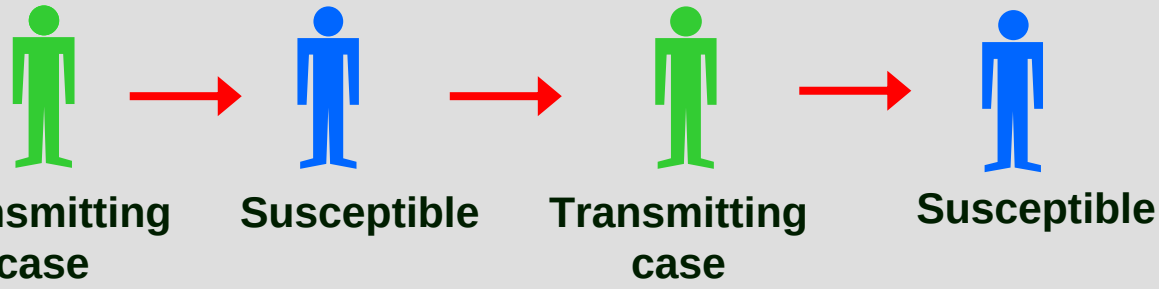
Community Immunity - I

Sustained transmission



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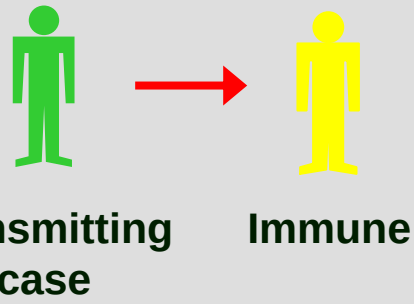
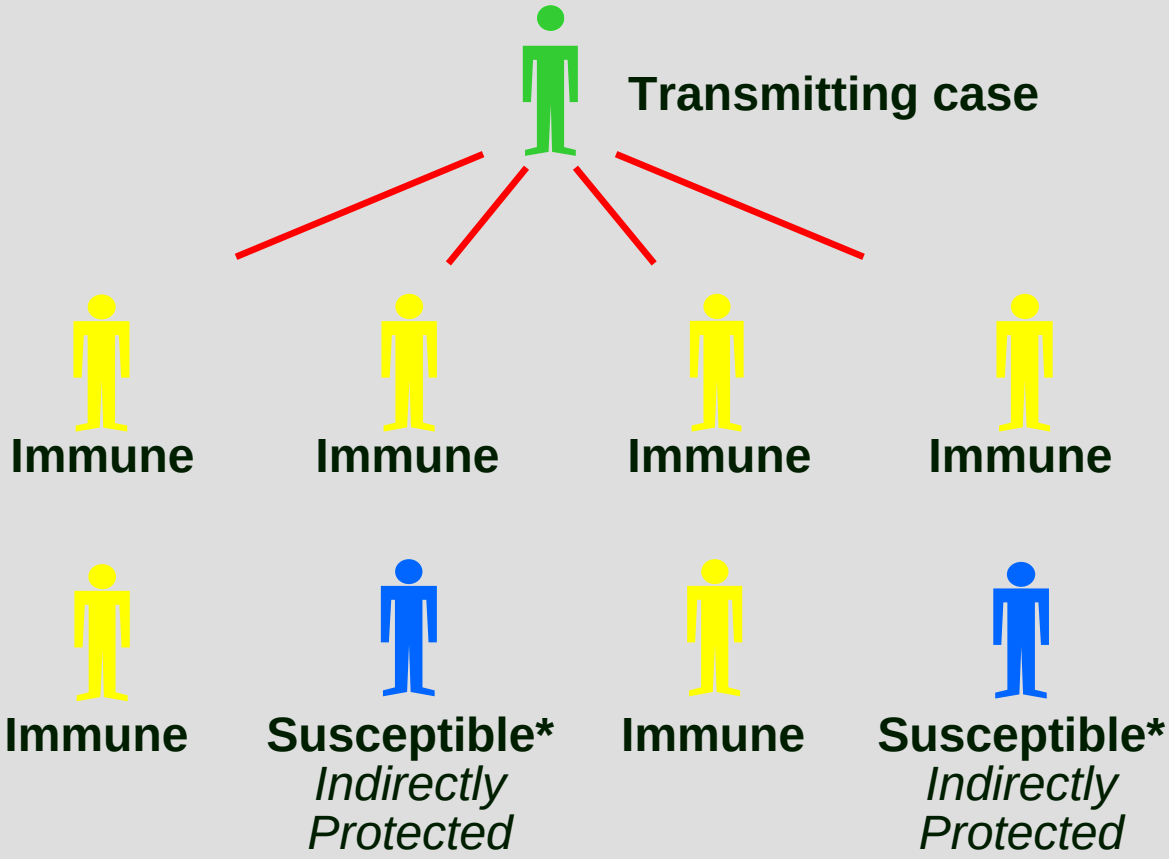


Adapted from Orenstein, 2005

Community Immunity – II



*Susceptible because: not immunized, vaccine failure; or vaccine contraindicated

Adapted from Orenstein, 2005

History of US School Immunization Laws

1804 - Massachusetts passed laws requiring populations be vaccinated against smallpox

1855 - Massachusetts passed first compulsory school immunization law

1905 - US Supreme Court upheld compulsory population vaccination -- Jacobson v Massachusetts

1922 - US Supreme Court upheld constitutionality of school immunization requirements

Adapted from Orenstein, 2005

1905 – Jacobson *v*. Massachusetts

Plaintiff Jacobson:

Right of every free man to care for his own body and health in such a way as to him seems best.

Justice Harlan:

No absolute right to be wholly freed from constraint. Organized society could not exist without manifold restraints.

1905 – Jacobson *v.* Massachusetts

Justice Harlan:

Limits based on “the necessity of the case”; not exceed what is reasonably required for the safety of the public.

Compulsory measures should not pose a health risk to the subject; must not be arbitrary and oppressive.

Exclusion to Enforce School Laws

Measles in LA – 1977

2 deaths, 3 encephalitis, numerous pneumonia cases and hospitalizations

March 31, 1977

Order to exclude children without proof of immunization by May 2, 1977

May 2, 1977

~50,000 / 1.4 million without proof of immunity excluded

Most back with proof within days

Adapted from Orenstein, 2005

Measles in 6 States Strictly Enforcing School Laws vs. Other States, 1978

	Measles Incidence per 100,000 <18 yrs	
	1977	**1978***
6 Enforcing States	40.6	2.7
Other States	90.3	35.2

*1st 31 weeks

MMWR 1978;27:303-4

Areas with High versus Low Measles[1]: Differences in Immunization Laws & Enforcement

	Low	High
Number of areas	13	10
Statewide laws	12 (92%)	9 (90%)
Mean duration of existence	6.4 yr	6.8 yr
Covers school entry	12 (92%)	9 (90%)
Covers all grades[2]	6 (46%)	0 (0%)
School exclusion[2]	10 (77%)	0 (0%)

[1]Am J Public Health 1981; 71:270-4
[2] $p<0.025$

Adapted from: Orenstein WA and Hinman AR. *Vaccine* 1999; 17(S3):S19-S24.

School/Day Care Immunization Requirements

	60's	70's	80's	90's	00's
Smallpox	✓				
Diphtheria	✓	✓	✓	✓	✓
Tetanus	✓	✓	✓	✓	✓
Pertussis	✓	✓	✓	✓	✓
Polio	✓	✓	✓	✓	✓
Measles		✓	✓	✓	✓
Rubella			✓	✓	✓
Mumps			✓	✓	✓
Hemophilus b				✓	✓
Hepatitis B				✓	✓
Varicella					✓
Hepatitis A					(✓)
(PCV 7)					?
(Influenza)					?

School Laws: Key Success Factors - I
Physicians' Support

School laws work because parents rely on physician recommendations in making their immunization decisions and most physicians... are supportive of compulsory immunization.

Orenstein WO, Hinman AR. *Vaccine* 1999;17(suppl 3):S19-S24

School Laws: Key Success Factors - II

Parents' Attitudes Toward Mandates

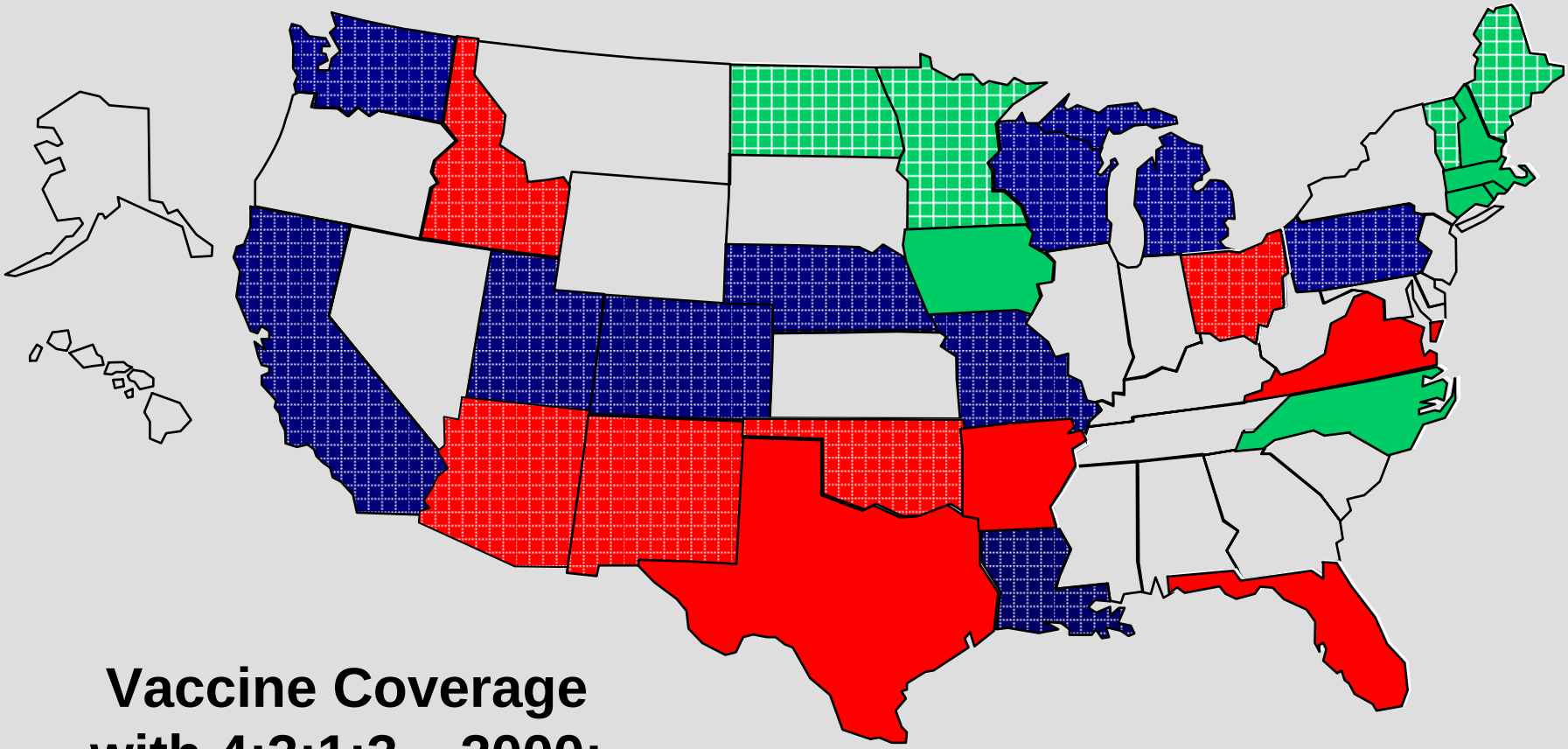
	Agree	Disagree
I am opposed to immunization requirements because:		
• *only I know what is best for my child*	**18%**	**75%**
• *go against freedom of choice*	**18%**	**75%**
Parents should be allowed to send their child to school even if *not* immunized	**14%**	**79%**

Gellin BG, Maibach E, Marcuse EK. *Pediatrics* 2000;106:1097-1102

Types of Exemptions to School Laws

Exemption Type	# of States
Medical	50
Religious	49
Personal or Philosophical	20

Philosophic Exemptions & Coverage



Vaccine Coverage with 4:3:1:3 – 2000:

- Highest 10 rates
- Lowest 10 rates

19 States allow philosophic exemptions for school or day care

Impact of Exemptions on Disease Transmission

Exemptors

Colorado

22.2 times more likely to acquire measles [+]

5.9 times more likely to acquire pertussis [+]

At least 11% of vaccinated children acquired measles from contact with an exemption [+]

National

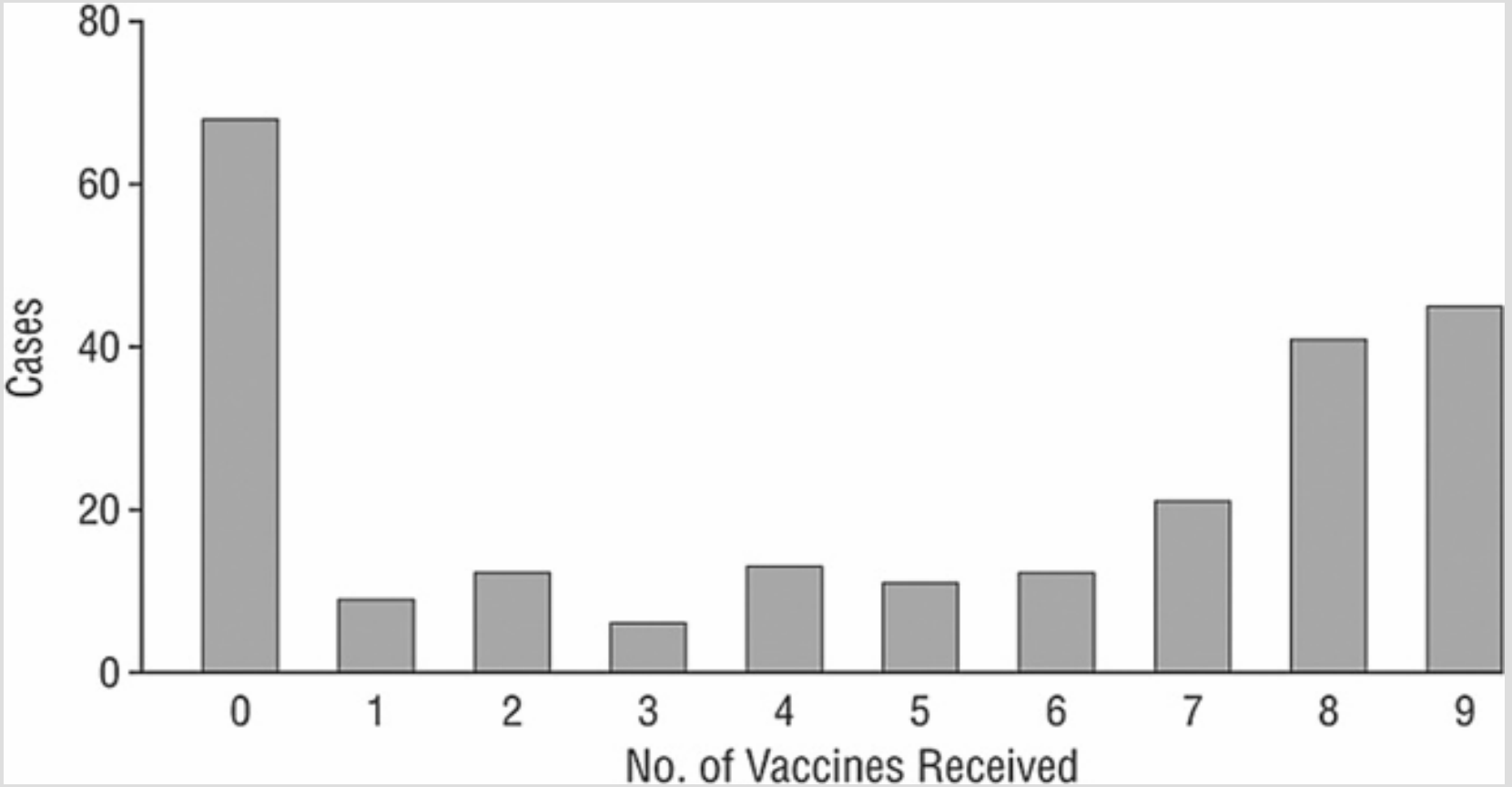
Exemptors 35 times more likely to acquire measles [++]

[+] Felkin DR et al. *JAMA* 2000; 284:3145-3150

[++] Salmon DA et al. *JAMA* 1999; 282 47-53

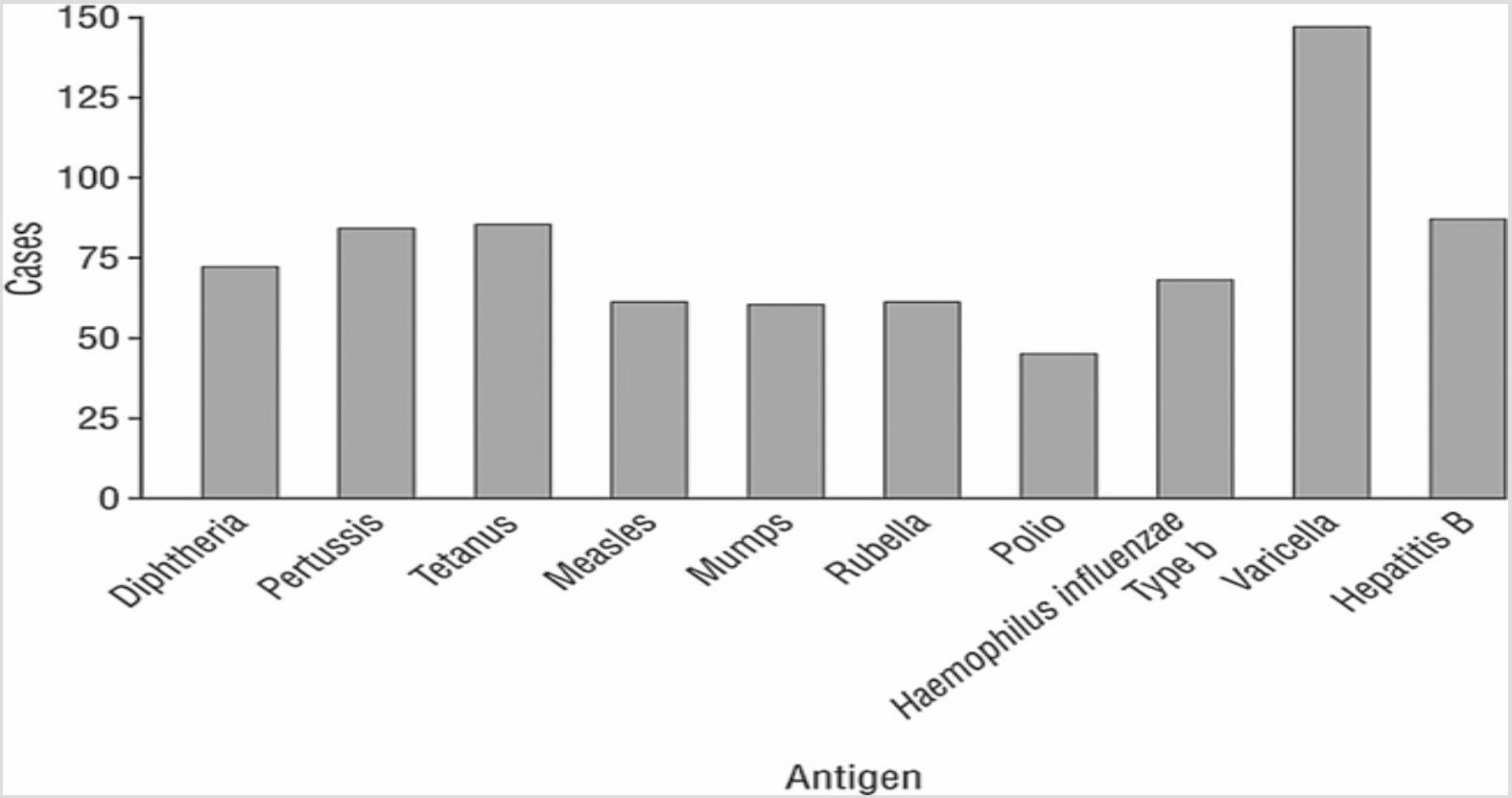
Adapted from Orenstein, 2005

Survey of 277 Parents of Children with Non-medical Exemptions in CO, MA, MO, WA: Recommended Vaccines Received



Salmon DA et al. *Arch Pediatr Adolesc Med*, 2005; 159(5):470–476

Survey of 277 Parents of Children with Non-medical Exemptions in CO, MA, MO, WA: Recommended Vaccines Not Received



Salmon DA et al. *Arch Pediatr Adolesc Med*, 2005; 159(5):470–476

Key Differences Between Parents of Exempt and Non-exempt Children

Survey of 277 children with non-medical exemptions in CO, MA, MO, WA and matched controls

	% exemptors	% non-exemptors	Odds Ratio
Too many immunizations	82%	20%	17
Weaken children's immune system	80%	32%	9
Better to be immune by being sick	51%	11%	9
Healthy children do not need immunizations	26%	2%	14
Immunizations do more harm than good	35%	4%	13
Freedom of choice critical	51%	9%	11
Parents should be allowed to send unvaccinated children to school	77%	24%	11

Salmon DA et al. *Arch Pediatr Adolesc Med*, 2005: 159(5):470-476
Adapted from Orenstein, 2005

Differences Between Exempt and Non-Exempt Children - II

Survey of parent of 277 children with non-medical exemptions in CO, MA, MO, WA and matched controls

	% exemptors	% non-exemptors	Odds Ratio
Vaccines one of safest medicines	11%	44%	0.16
Immunizations getting better and safer	27%	68%	0.18
Vaccines strengthen immune system	14%	52%	0.15
Immunization requirement protect against disease from unvaccinated children	39%	78%	0.17

From: Salmon DA et al. *Arch Pediatr Adolesc Med*, 2005; 159(5):470–476
Adapted from Orenstein, 2005

Origins of Immunization Hesitancy I

Social & Cultural

- Decline in vaccine-preventable diseases
- Recognition of the present limits of medicine, science, technology
- Resurgence of complementary & alternative medicine
- Malpractice and product liability litigation

Adapted from Kane MA, *Vaccine* 1998;S73-78

Origins of Immunization Hesitancy II

Science, Media & The Internet

- Distortion of scientific process
  Science hypothesis – hypothesis test – accept – reject – refine
  media: hypothesis "validated" by repetition
- Differing criteria for causality:
  medical; legal; public opinion
- Challenge of risk communication:
  power of case reports
  science vs. freelance and feature writers; talk radio
- 21st century access to media, internet;
  source credibility, media concept of balance, utility to media of controversy

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Adapted from Kane MA, *Vaccine* 1998;S73-78

Postmodernism: Public Health

In post-modern medicine risks receive much higher priority.

This is not an example of proponents of scientific health care being rational and others being irrational; rather it is an example of how multiple rationalities and truths now prevail…

Adapted from Muir Gray, JA. *Lancet* 1999; 354:1550-1553

The Trade-offs

- What is the balance between:
  - the state's duty to protect the public health
  - and the right of an individual to choose?

- What disease risk balanced by what assurance of vaccine safety justifies a mandate?

Define the Rationale For A Mandate

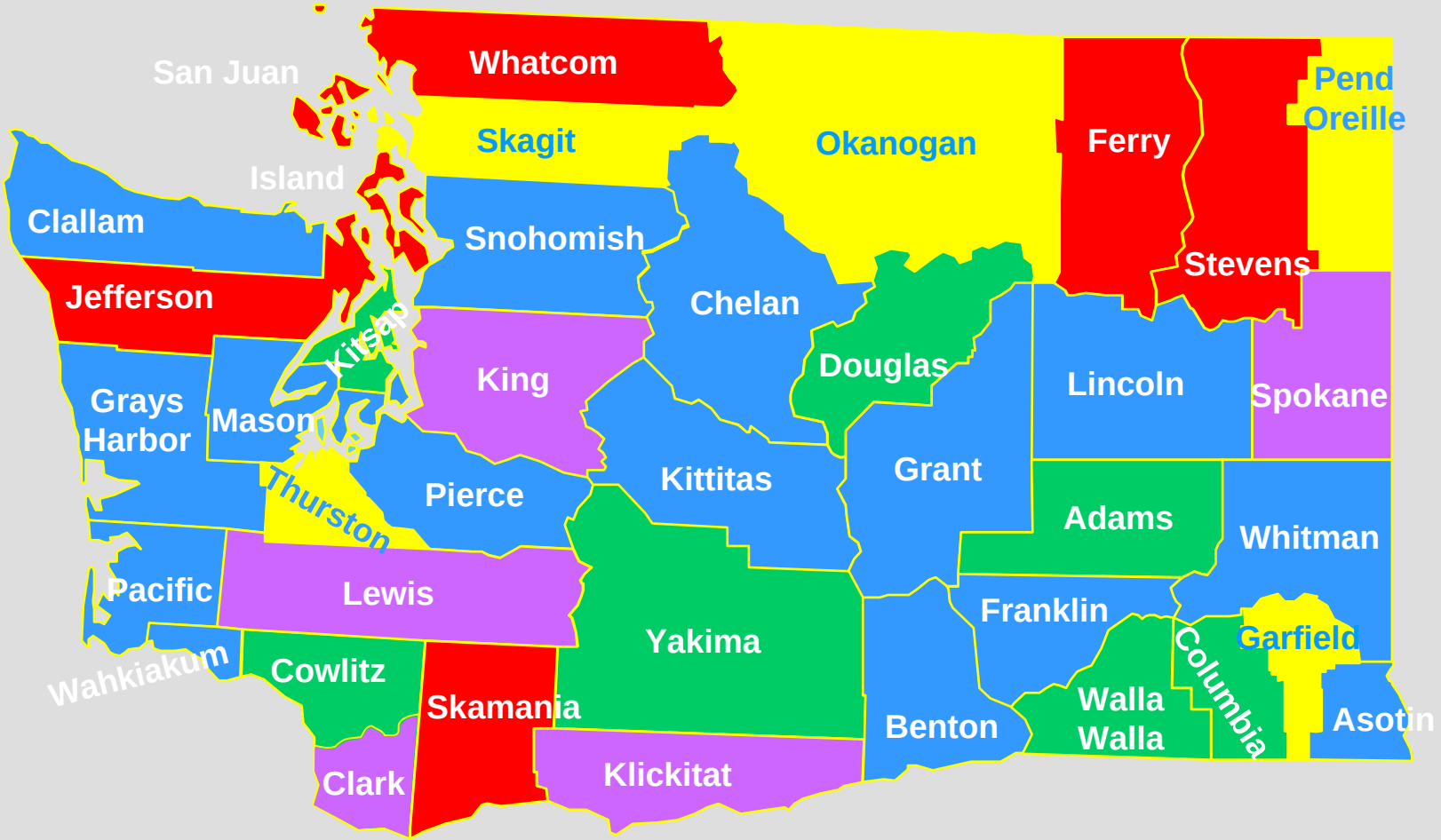
- Differentiate health risks & benefits for the individual and for the community
- What constitutes a public health risk or benefit?
  - Contagion or epidemic
  - Illness, injury, disability, death
  - Adverse effect on children
  - Cost of care, disability

Which Rationale Applies?

-Threat of Contagion
- Cost to Society
- State's Interest in Protecting Children

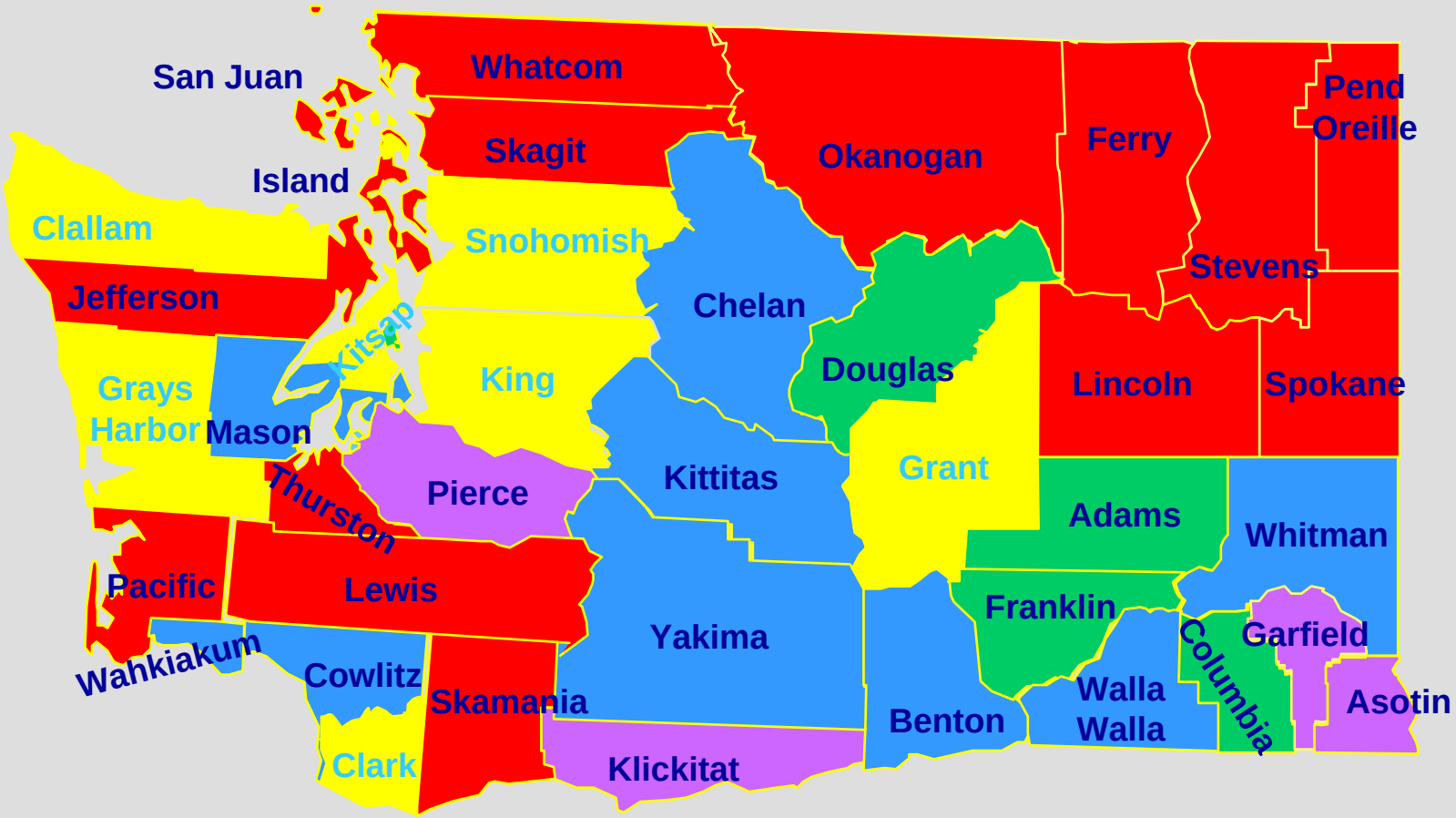
diphtheria	measles	hemophilus b	varicella
pertussis	mumps	hepatitis B	hepatitis A
tetanus	rubella		(PCV 7)
polio			(influenza)

WA State Counties' School Exemption Rates 1999



Source: WA State Department of Health

WA State Counties' School Exemption Rates 2004



Source: WA State Department of Health

School Immunization Exemptions WA State 2002

In 236 WA State primary schools with ≥ 5% of total enrollment exempt and ≥ 5 exemptors:

- 95% of ~5000 exemptions were personal
- 50% (119/236) of schools used exemptions to comply with immunization law

DeHart P, et al. WA State DOH, 2002

Conclusions I: Immunization Mandates

1. Valuable public health tool in U.S.
2. Should be limited to diseases of indisputable public health importance
3. Rationale should be clearly stated
4. Require strong medical community support
5. Should involve lay public

Role of industry

Conclusions II:
Immunization Exemptions

1. Exemptors more likely to develop and spread diseases such as measles and pertussis
2. Exemptors' parents vary in which vaccinations they accept; their beliefs differ from non-exemptors
3. Exemption levels appear to relate to the administrative requirements for obtaining exemptions
4. WA State exemptions are increasing; a substantial proportion appear to be 'convenience' exemptions

Conclusions III

Immunization Exemptions:

5. Eliminate schools' financial incentive for using exemptions
6. Monitor exemption rates; understand reasons
7. Address erroneous perceptions of risk
8. Ensure that exemption is a thoughtful process, avoiding onerous or irrelevant hurdles